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REGULATIONS OF SOME COUNTRIES ON HUMAN GENETIC ENGINEERING OR GENE MODIFICATION

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INTRODUCTION

Genetic engineering or genetic modification is the process of modifying the genes of living organisms using biotechnology. Genetic engineering is a scientific discipline that uses genetic and biochemical methods to produce new compounds that do not exist in nature for specific purposes. In 1972, scientist P. Bergi created a hybrid DNA molecule in a test tube.[1] The foundation of genetic engineering has been laid since the creation of the human race. Genetic engineering is a complementary research aimed at creating cells, tissues, and bodies that synthesize biologically active and other substances that meet human needs by transferring genes responsible for specific proteins and functions from one organism to another and changing the genetic information.

Genetic engineering [2]is a complex technology used to transfer genes from one organism to another. Animals and plants produced through genetic engineering are generally [3]called genetically modified organisms. In short, an animal that has had a new gene inserted into it is called a transgenic or gene-transplanted [4]animal. On the other hand, if its own genes have been removed or replaced, [5]it is called a knockout or gene-silenced animal.

This scientific progress can be attributed to experiments on the subject. [6]However, its use and testing on humans is prohibited internationally. Because the final consequences of the experiment are currently impossible to calculate. At the same time In terms of law, certain principles and human rights are at stake.

[1] England - In vitro
[2] England - Genetic engineering
[3] England - Genetically modified organism
[4] England - Transgenic
[5] England - Knockout
[6]https://legaldata.mn/b/1717

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The United Nations Educational, Scientific and Cultural Organization adopted the Universal Declaration on the Human Genome and Human Rights in 1997. The Declaration is a non-binding document, but it calls on member states to adhere to it. The Declaration leaves open the freedom of research, analysis and selection. While a few countries grant special licenses for the import and export of embryos and stem cells, others prohibit them outright. It is questionable whether genetic engineering should be permitted for the health and well-being of humans internationally.

It is worth noting that while human genetic science is making significant progress in Mongolia, detailed legislative regulations are still lacking.

It is worth emphasizing that human genetic engineering has become a phenomenon that has produced real results, not just a figment of human imagination, and that there is a need for its legal regulation.

1. Legal Issues Surrounding The Engineering Or Modification Of Human Genes

Genetic engineering has already been tested on animals, but scientists are still debating its benefits. However, there is an international ban on human genetic engineering or modification. Accordingly, international and regional declarations have been adopted, and some countries are following them and incorporating them into their laws.

For example, human genetic engineering or modification may violate the following principles and human rights:

- Human dignity.

  Article 1 of the Universal Declaration of Human Rights states that “Everyone is born free and equal in dignity and rights...” [7]It is also stated in the International Covenant on Civil and Political Rights [8], the Declaration on Economic, Social and Cultural Rights, “...recognize the inherent dignity and the equal and inalienable rights...” [9], Article 16(1) of the Convention on the Rights of the Child, “...no unlawful attacks on the dignity and

[7] https://legalinfo.mn/mn/detail/1271
[8] https://legalinfo.mn/mn/detail/1257
[9] https://legalinfo.mn/mn/detail/1284

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honor of any person shall be permitted" [10], the International Convention on the Elimination of All Forms of Racial Discrimination [11], the Convention on the Elimination of All Forms of Discrimination against Women [12], and the Convention against Torture and Other Cruel, Inhuman or Degrading Treatment or Punishment [13]. The Universal Declaration on the Human Genome and Human Rights states that "recognition of the genetic diversity of the human race shall not give rise to any interpretation of a social or political nature which may infringe upon the inherent dignity of the human race" [14]and states in Article 2 (a) of the Declaration that "everyone shall have the right to respect for the dignity and rights of all human beings, regardless of their genetic characteristics." Article 3 of the Declaration on Bioethics and Human Rights states that "…the interests and well-being of the individual shall prevail over scientific and public interests." Regionally, this is reflected in the Oviedo Convention [15], the European Union Charter of Human Rights [16], and the African Charter on Human and Peoples' Rights.

Human dignity is inviolable, and genetic engineering or genetic modification must be treated with respect, both at the research and clinical application levels. Discrimination and stigmatization based on genetic characteristics and qualities must be prohibited, genetic uniqueness and diversity must be respected, and the interests of the individual must prevail over other interests and scientific achievements.

- The right to bodily integrity.

  The right is a broad concept and is distinct from the right to life. It can be simply understood as the right to ensure the integrity of one's genes, to be free from external influences, and to be free from the influence of other factors on one's genes. The European Convention on Human Rights prohibits serious and minor forms of interference with the physical and mental integrity of a person, as well as any medical treatment without consent. The right to physical integrity is defined as a direct restriction on the freedom to conduct scientific research. demonstrate that the right to bodily integrity applies to embryos and even future generations.

[10] https://legalinfo.mn/mn/detail/1276
[11] https://legalinfo.mn/mn/detail?lawId=1242
[12] https://legalinfo.mn/mn/detail/1285
[13] https://legalinfo.mn/mn/detail/1156
[14] The Human Genome and the Universal Declaration of Human Rights, 1997. Preamble.
[15] The video convention
[16]Charter of Fundamental Rights of the European Union, 2000/C 364/01.

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- The right to enjoy the benefits of scientific progress.

  Researchers have the right to benefit from genetic engineering research, limited only by personal privacy. However, some countries do not recognize this research in law, which limits their ability to exercise this right. Science must be protected from misuse and negative impacts.

  Other human rights issues will also arise, such as the right to non-discrimination and the right to health protection.

2. Legal regulation of human genetic engineering in some countries

USA

The United States does not prohibit genetic engineering, but it does impose restrictions on funding for research involving embryos, particularly embryonic genetic engineering. The law prohibits funding for research that "risks the destruction, injury, or death of human embryos beyond that permitted for research on the fetus in the womb." The Office of Science and Technology Policy is working to reform the [17]federal regulatory framework for biotechnology products and to clarify the regulatory policy for genetic engineering and its applications. [18]In parallel, states have explicitly prohibited it through domestic legislation. For example, California's Health and Safety Act prohibits "the transfer of human cells to non-human ova."[19]

RUSSIA

The Civil Code of the Russian Federation introduced a provision in 2014 prohibiting the patenting of methods for altering the genetic integrity of human embryos. The Law on the Protection of [20]Citizens ' Health also provides that a woman undergoing medical examination and diagnosis has the right to receive information about the results of her genetic testing.[21]

In 2016, the use of genetic engineering methods on human tissues and cells was prohibited, except for genetic diagnostics and gene therapy. In addition, Article 3, Section 4 of the Biomedical Products Law states that "the creation of human embryos for the purpose of

[17]Office of Science and Technology Policy
[18] https://www.fda.gov/downloads/Food/IngredientsPackagingLabeling/GEPlants/UCM537311.pdf
[19] California Health and Safety Code, Sec. 24185-24187.
[20] Part 4 of Article 1349 of the Civil Code of the Russian Federation. 2, 3 as amended by Federal Law No. 35 of March 12, 2014.
[21] Russian Citizens Health Protection Law No. 5487-I, 22 July 1993 (as amended 2009), Art.35(4).

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producing biomedical cell products is prohibited."[22]

ISRAEL

Israel has a law prohibiting genetic intervention, which prohibits certain types of genetic activities based on moral, legal, social, scientific, and human dignity concerns. However, it does take into account the freedom of scientific research to advance medical science.[23]

The above law prohibits the implantation of intentionally genetically modified reproductive cells for the purpose of creating a human being (embryo gene therapy) . Violations are punishable by criminal liability and up to four years in prison. However, genetic engineering is permitted with the approval of the Minister, provided that it does not violate human dignity and within the recommendations of the Advisory Committee and the conditions set by it.

INDIA

The main law related to genetic engineering or editing is the Preconception and Prenatal Diagnostic Methods Act of 1994. [24]The purpose of this law is to prohibit sex selection and [25]specifies the types of diagnostics.

There are two sets of guidelines for genetic engineering or editing issued by the Medical Research Council. [26]The first sets out specific principles for genetic research. The second is the draft National Guidelines for Stem Cell Research 2017. These guidelines are not binding and are recommendations.

JAPAN

Japan's gene editing regulations are set out in the 2002 Guidelines for Clinical Research on Gene Therapy. The guidelines define "gene therapy as the manipulation of genes or cells into which genes have been introduced into the human body for the purpose of treating a disease." [27]Clinical trials of gene therapy must meet a number of requirements, including the treatment

[22] " The Regulation of Genome Editing and Human Reproduction Under International Law, EU Law and Comparative " Law.Dr. Rumiana Yotova.June 2017.p 50.
[23] Prohibitionof Genetic Intervention (Human Cloning and Genetic Manipulation of Reproductive Cells) Law 5759-1999, Art.1 .
[24] Pre -Conception and Pre-Natal Diagnostic Techniques Act 1994 (as amended 2002).
[25] Chromosomal disorders, hereditary metabolic diseases, hemoglobinopathies, sex-linked genetic diseases, congenital anomalies, and other disorders and diseases determined by the Central Control Council.
[26] http://www.icmr.nic.in/ethical_guidelines.pdf
[27] Japan Guidelines on Gene Therapy Clinical Research 2002 (as amended 2008), s.2(1).

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of serious genetic disorders, cancer, acquired immunodeficiency syndrome, and other life-threatening diseases or disorders that significantly impair physical function. The guidelines explicitly prohibit the editing of embryos.

GERMANY

The German law on the protection of human embryos regulates gene editing. Section 5, paragraph 1 of the law states that "Anyone who artificially alters the genetic information of human embryos shall be punished with imprisonment for a term of up to five years or a fine", and Section 2 of the law states that "Anyone who uses human gametes with artificially altered genetic information for the purpose of procreation shall be punished." Section 3 also provides for the confiscation of the proceeds from such use.[28]

MEXICO

Mexico does not have a separate law on human genetics, but it is regulated by the General Health Law, passed in 1997. The law recognizes infertility treatment and reproductive rights, and prohibits gene editing and other uses.

The General Law on Health defines human genes as "the genetic material that contains all the genetic information that characterizes the human species and is the basis of the fundamental unity and diversity of human biology [29]." It also stipulates that knowledge related to human genes is the heritage of humanity, and that scientific and technological development must be directed towards the protection of health and human rights must be given priority.

Article 154 of the Criminal Code states that "any person who alters the genotype of a human being by altering the human gene for purposes other than the elimination or prevention of a serious disease or condition shall be punished by imprisonment for a term of up to six years, or by deprivation or suspension of the right to practice their profession." [30]The Criminal Code also provides for civil legal consequences, compensation for damages, and payment of maintenance fees arising from the birth of a child as a result of an act prohibited by the Criminal [31]Code.

[28]https://www.bundesgesundheitsministerium.de/fileadmin/Dateien/3_Downloads/Gesetze_und_Verordnungen/GuV/E/ESchG_EN_Fassung_Stand_10Dez2014_01.pdf
[29]General Law on Health. Art.103.
[30]Art. 154 (3) Código Penal para el Distrito Federal
[31]Art. 15 5(3) Código Penal para el Distrito Federal

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AUSTRALIA

Australia criminalized genetic modification in 2002 with the Human Reproduction Prohibition Act. The legislation criminalizes the intentional or intentional modification of a person's genetic makeup in a way that is likely to be passed on to offspring. The offense carries a maximum penalty of 15 years in prison. It [32]also criminalizes the import, export, or possession of embryos that are prohibited by law.

FRANCE

French Civil Code prohibits research aimed at modifying human embryos, altering genetic characteristics, or preventing or treating genetic diseases. [33]The Bioethics Code also states that methods for modifying human genetic characteristics cannot be patented.

By criminal law It defines eugenics [34]and reproductive cloning as crimes against humanity, and stipulates that anyone who practices eugenics to organize human selection will be punished with thirty years in prison and a fine of 7,500,000 euros.[35]

The laws and regulations of the above countries contain specific regulations on human genetic engineering, but they have not reached a consensus. Accordingly, since the results of human genetic engineering have not been finally confirmed, each country has openly legalized the right to prohibit, restrict, and conduct research within the framework of certain permits.

CONCLUSION

Allows for certain restrictions to be imposed within the framework of ensuring the right to protect human well-being and health, and the right to conduct research.

Human genetic engineering or modification is a controversial issue in many scientific disciplines. Because the conclusions about how its consequences will be affected are still speculative. Moreover, since it is a legal issue directly related to human rights, it is impossible to resolve genetic engineering activities based on speculation. By recognizing it in law, there

[32]Art. 15, Prohibition of Human Cloning for Reproduction Act 2002 (as amended 2008).
[33]Art. 16-4 Code civil (1804) (as amended March 2017).
[34]Historically, eugenicists have sought to alter the human gene pool by eliminating individuals or groups deemed inferior or promoting those deemed superior. In recent years, the term has been revived in bioethical discussions about the use of new technologies such as CRISPR and genetic screening, and there has been a tendency to view these technologies as eugenics.
[35]Art. 214-1, Penal Code (as amended April 2017).

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is a risk that if human rights are violated, the consequences will not be remedied.

However, in some foreign countries, genetic engineering or cloning is only accepted for research purposes when it comes to protecting human well-being and health.

Judging from the legal regulations of some countries, the scope of genetic engineering has been defined as follows:

1. Human genetic research and modification ;
2. of the process of human embryogenesis and its transformation ;
3. It can be classified as general research, or research into the genes of other people, not just reproductive ones.

The laws of the United States, Russia, Israel, India, Japan, Germany, Mexico, Australia, and France prohibit human genetic engineering or modification through separate laws and related laws. In some countries, it is permitted only for research purposes and is carried out under the approval of government authorities or under the supervision of government agencies. In addition, there are provisions for criminal liability and civil compensation for the performance of such prohibited activities.

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